K131090
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JUL 0 3 2013

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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
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510(k) Summary (in accordance with 21 CFR 807.92)

1. Company

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Tel: +81 (76) 274-2468
Fax: +81 (76) 274-2484

2. Contact Person

Hiroaki Hashimoto

3. Date of Summary

April 15th, 2013

4. Device Information

- Trade Name/Model: RadiForce MX215
- Common Name: 2MP Color LCD Monitor
- Classification Name: System, Image Processing, Radiological
- Regulation Number: 21 CFR 892.2050, Product Code LLZ

5. Predicate Device

- 2MP Color LCD Monitor, RadiForce RS210 (K092613)

6. Device Description

RadiForce MX215 is a color LCD monitor for viewing medical images other than those of mammography. The color panel employs in-plane switching (IPS) technology allowing wide viewing angles and the matrix size (or resolution) is 1,200 x 1,600 pixels (2MP).

Since factory calibrated display modes, each of which is characterized by a specific tone curve (including DICOM GSDF), a specific luminance range and a specific color temperature, are stored in lookup tables within the monitor, the tone curve is e.g. DICOM compliant regardless of the display controller used.

RadiCS is application software to be installed in each workstation offering worry-free quality control of the diagnostic monitors including the RadiForce MX215 based on the QC standards and guidelines and is capable of quantitative tests and visual tests defined by them. The RadiCS and its subset, RadiCS LE, are included in this 510(k) submission as an accessory to the RadiForce MX215.

7. Intended Use

This product is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. It does not support the display of mammography images for diagnosis.

8. Comparison of Technological Characteristics

The comparison table below enumerates information derived from the product brochures of the each device and different technological characteristics are discussed:

Attributes	Eizo RadiForce MX215	Eizo RadiForce RS210	Explanation of Differences
Display Performance/Specifications			
Screen technology	TFT Monochrome LCD Panel (IPS)	TFT Monochrome LCD Panel (IPS)	-
Viewing angle (H, V)	H: 178°, V: 178°	H: 170°, V: 170°	Eizo uses typical data for very low contrast provided by the panel manufacturers
Active screen size	324.0 mm x 432.0 mm	432.0 mm x 324.0 mm	-
Resolution	2MP (1,200 x 1,600)	2MP (1,600 x 1,200)	
Aspect ratio	3 : 4	4 : 3	-
Pixel pitch	0.270 mm x 0.270 mm	0.270 mm x 0.270 mm	-
Maximum luminance	420 cd/m^2	300 cd/m^2	-
DICOM calibrated luminance	180 cd/m^2	150 cd/m^2	
Contrast ratio	1500 : 1	1000 : 1	Eizo uses typical contrast ratio data provided by panel manufacturers.
Backlighting	LED	CCFL	See main text.
Display Colors	From a palette of 68 billion colors: - 10-bit (DisplayPort): 1.07 billion colors (maximum) - 8-bit colors: 16.77 million colors	From a palette of 68 billion colors: - 10-bit (DisplayPort): 1.07 billion colors (maximum) - 8-bit colors: 16.77 million colors	-
Luminance non-uniformity compensation	Digital Uniformity Equalizer	Digital Uniformity Equalizer	-
Video Signal Input			
Input video signals	DVI-I x 1, DisplayPort x 1	DVI-I x 2 , DisplayPort x 1	-
Scanning Frequency (H, V)	Digital : 31 - 76 kHz / 59 - 61 Hz (VGA Text: 69 - 71 Hz) Analog : 26 - 80 kHz / 49 - 76 Hz	Digital : 31 - 100 kHz / 59 - 61 Hz (VGA Text: 69 - 71 Hz) Analog : 31 - 100 kHz / 49 - 86 Hz (1600 x 1200: 49 - 61 Hz) , Frame synchronous mode: 59 - 61 Hz	-

Power Related Specifications			
Power Requirements	AC 100 - 120 V, 200 - 240 V: 50 / 60 Hz	AC 100 - 120 V, 200 - 240 V: 50 / 60 Hz	-
Power Consumption / Save Mode	48 W / Less than 0.5 W	64 W / Less than 1 W	-
Power Management	Digital: DVI DMPM, DisplayPort 1.1a Analog: VESA DPM	Digital: DVI DMPM, DisplayPort 1.1a Analog: VESA DPM	-
Miscellaneous Features/Specifications			
QC software	RadiCS	RadiCS	-
Sensors	Backlight Sensor (BS), Integrated Front Sensor (IFS), Presence Sensor (PS)	Backlight Sensor	Among two sensors not implemented on RS210, only the IFS has something to do with the maintenance or the calibration; the PS detects the absence of the user to trigger the power saving mode of the monitor. The IFS enables automatic grayscale calibration by measuring the luminance at the screen surface.
USB Ports / Standard	1 upstream, 2 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	-
Dimensions w/o stand (W x H x D)	360 x 485 x 64 mm	472 x 373 x 69 mm	Different housing design due to the different panel size.

For the substantial equivalence determination, only the difference of the backlight technologies needs further evidences by performance testing.

9. Performance Testing

The following bench tests were performed on the RadiForce MX215.

- Verification of the conformance to DICOM GSDF as specified in *Assessment of Display Performance for Medical Imaging Systems* by AAPM Task Group 18 (TG18 guideline)
- Measurement of the luminance non-uniformity characteristics of the display screen as specified in the TG18 guideline
- Measurement of the chromaticity non-uniformity characteristics of the display screen as specified in the TG18 guideline
- Measurement of the chromaticity at the center of the display screen at 5%, 50% and 95% of the maximum luminance as specified in *Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) Submissions*
- Visual check of presence or absence of miscellaneous artifacts on the display screen as specified in the TG18 guideline
- The maximum number allowed for each type of pixel defects/faults

The test results showed that the RadiForce MX215 has display characteristics equivalent to those of the predicate device, RadiForce RS210.

Besides, the display characteristics of the RadiForce MX215 meet the pre-defined criteria when criteria are set.

No animal or clinical testing was performed on the RadiForce MX215.

10. Conclusion

The 2MP Color LCD Monitor, RadiForce MX215 has the same intended use as the predicate device but has one different technological characteristics. Bench testing showed that the safety and effectiveness of the RadiForce MX215 was not affected by the difference of the technological characteristics. Therefore, the RadiForce MX215 was determined to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 3, 2013

EIZO Corporation
% Mr. Hiroaki Hashimoto
Manager
153 Shimokashiwano, Hakusan
Ishikawa 924-8566
JAPAN

Re: K131090
Trade/Device Name: 2MP Color LCD Monitor, RadiForce MX215
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: April 18, 2013
Received: May 2, 2013

Dear Mr. Hashimoto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

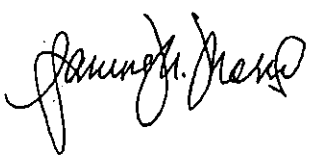
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131090

Device Name: 2MP Color LCD Monitor, RadiForce MX215

Indications for Use: This product is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners.
It does not support the display of mammography images for diagnosis.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K131090